

In re Application of: Michal DANIELY et al
Serial No.:10/771,440
Filed: February 5, 2004
Office Action Mailing Date: August 10, 2007

Examiner: Duffy, Bradley
Group Art Unit: 1643
Attorney Docket: 26003

In the Claims:

1-36. (Canceled)

37. (Currently Amended) A method of identifying transitional cell carcinoma cells in a urine sample comprising:

(a) staining nucleated cells of the urine sample by ~~at least two staining methods—May-Grünwald-Giemsa, Giemsa, Papanicolau or Hematoxylin-Eosin~~ to thereby obtain stained nucleated cells, and;

(b) ~~staining said stained nucleated cells resultant of step (a) by FISH, to thereby obtain stained nucleated cells, and;~~

(c) ~~imaging said stained nucleated cells resultant of steps (a) and (b) by at least two imaging modes, wherein one imaging mode of said at least two imaging modes being different from another imaging mode of said at least two imaging modes.~~

to thereby identify the transitional cell carcinoma cells in the urine sample.

38. (Canceled)

39. (Original) The method of claim 37, wherein the transitional cell carcinoma cells are associated with bladder cancer and/or kidney cancer.

40. (Original) The method of claim 37, wherein the urine sample is obtained via voided urine or catheterization.

41-53. (Canceled)

54. (Currently amended) The method of claim 37, wherein step (b) is effected using an automated cell imaging device capable of at least dual imaging.

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55. (Currently amended) A method of diagnosing bladder cancer in a subject, the method comprising:

- (a) obtaining a urine sample from the subject;
- (b) staining nucleated cells of said urine sample by May-Grünwald-Giemsa, Giemsa, Papanicolau or Hematoxylin-Eosin ~~at least two staining methods to~~ thereby obtain stained nucleated cells, and;
- (c) staining said stained nucleated cells resultant of step (b) by FISH to ~~thereby obtain stained nucleated cells, and;~~
- (d) imaging said stained nucleated cells resultant of steps (b) and (c) by at ~~least two imaging modes, wherein one imaging mode of said at least two imaging modes being different from another imaging mode of said at least two imaging modes,~~

to thereby determine the presence or absence of cancerous cells within said stained nucleated cells, wherein presence of said cancerous cells is indicative of a positive cancer diagnosis.

56. (Canceled)

57. (Original) The method of claim 55, wherein the urine sample is obtained via voided urine or catheterization.

58-71. (Cancelled)

72. (Currently amended) A method of identifying transitional cell carcinoma cells in a urine sample comprising:

- (a) staining nucleated cells of the urine sample by May-Grünwald-Giemsa, Giemsa, Papanicolau or Hematoxylin-Eosin ~~one staining method of at least two staining methods to~~ thereby obtain stained nucleated cells ~~by said one staining method,~~ and subsequently

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(b) imaging said stained nucleated cells resultant of step (a); and subsequently

(c) staining said stained nucleated cells resultant of step (a) by FISH ~~another staining method of said at least two staining methods~~ to thereby obtain stained nucleated cells ~~by said another staining method~~; and subsequently

(d) imaging said stained nucleated cells resultant of step (c); and subsequently

(e) simultaneously viewing said stained nucleated cells resultant of steps (a) and (c)

to thereby identify the transitional cell carcinoma cells in the urine sample.

73. (Currently amended) A method of diagnosing bladder cancer in a subject, the method comprising:

(a) obtaining a urine sample from the subject;

(b) staining nucleated cells of said urine sample by May-Grünwald-Giemsa, Giemsa, Papanicolaou or Hematoxylin-Eosin ~~one staining method of at least two staining methods~~ to thereby obtain stained nucleated cells ~~by said one staining method~~, and subsequently

(c) imaging said stained nucleated cells resultant of step (b); and subsequently

(d) staining said stained nucleated cells resultant of step (b) by FISH ~~another staining method of said at least two staining methods~~ to thereby obtain stained nucleated cells, ~~by said another staining method~~; and subsequently

(e) imaging said stained nucleated cells resultant of step (d); and subsequently

(ef) simultaneously viewing said stained nucleated cells resultant of steps (b) and (d)

to thereby determine the presence or absence of cancerous cells within said stained nucleated cells, wherein presence of said cancerous cells is indicative of a positive cancer diagnosis.

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74. (New) The method of claim 37, wherein said FISH is effected using a FISH probe to a pericentromeric region of chromosome 3, 7 and 17.

75. (New) The method of claim 37, wherein said FISH is effected using a FISH probe to a pericentromeric region of chromosome 3, 7 and 17 and a FISH probe to chromosome 9p21.

76. (New) The method of claim 55, wherein said FISH is effected using a FISH probe to a pericentromeric region of chromosome 3, 7 and 17.

77. (New) The method of claim 55, wherein said FISH is effected using a FISH probe to a pericentromeric region of chromosome 3, 7 and 17 and a FISH probe to chromosome 9p21.

78. (New) The method of claim 72, wherein said FISH is effected using a FISH probe to a pericentromeric region of chromosome 3, 7 and 17.

79. (New) The method of claim 72, wherein said FISH is effected using a FISH probe to a pericentromeric region of chromosome 3, 7 and 17 and a FISH probe to chromosome 9p21.

80. (New) The method of claim 73, wherein said FISH is effected using a FISH probe to a pericentromeric region of chromosome 3, 7 and 17.

81. (New) The method of claim 73, wherein said FISH is effected using a FISH probe to a pericentromeric region of chromosome 3, 7 and 17 and a FISH probe to chromosome 9p21.